**REMARKS**

Claim 33 is pending in the application. Claim 33 has been rejected.

Reconsideration and withdrawal of the rejections set forth in the Office action dated July 20, 2001 are respectfully requested. The applicant petitions the Commissioner for a 3-month extension of time. A separate petition accompanies this amendment. The claim in this application is the subject of a motion to add this application to pending Interference No. 104,290.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "**Version With Markings to Show Changes Made**."

I. Priority Claim

Applicants submit that the continuing data presented in the Preliminary Amendment filed December 2, 1999 in the present application is correct. The present application is a continuation of application serial no. 09/364,203, now pending, which is a continuation of application serial no. 08/623,652, now U.S. Patent No. 5,935,123 (hereinafter "the '123 patent"), etc. The entire contents of the '123 patent are incorporated by reference in the present application. The present application has been amended to include Figures 13, 14, and 15 of the '123 patent.



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II. Amendments

A. Specification

The specification has been amended to correct an obvious typographical error. The specification has further been amended in accord with M.P.E.P. § 2163.07(b) to include text from column 6, lines 31-37; column 14, lines 34-67; and column 15, lines 1-28 of the '123 patent, which was properly incorporated by reference.

B. Claims

Claim 33 has been amended for clarity in accord with the Examiner's kind suggestion.

C. Drawings

The drawings have been amended in accord with M.P.E.P. § 2163.07(b) to include Figures 13, 14 and 15 of the '123 patent, which was properly incorporated by reference.

By these amendments, no new subject matter has been added.

III. Rejection under 35 U.S.C. §101

Claim 33 was rejected under 35 U.S.C. §101 as allegedly directed to non-statutory matter. Claim 33 has been amended in accord with the Examiner's kind suggestion. Reconsideration and withdrawal of the rejections under 35 U.S.C. §101 are respectfully requested.

IV. Rejections under 35 U.S.C. §112, second paragraph

Claim 33 was rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Specifically, the Examiner asserts that the claim is unclear as to the scope in that it recites tissue, which is non-statutory matter.



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Applicants have amended claim 33 in accord with the Examiner's kind suggestions.

Applicants respectfully submit that claim 33 is in full compliance with the requirements of 35 U.S.C. §112. Reconsideration and withdrawal of the rejections under 35 U.S.C. §112 are respectfully requested.

V. Rejections under 35 C.F.R. §102

Claim 33 was rejected under 35 U.S.C. §102(b) as allegedly anticipated by Rydell (U.S. Patent No. 5,007,908). This rejection is respectfully traversed.

A. The Present Invention

The present invention describes a probe system, which can be used in a non-invasive procedure to ablate a selected tissue mass, including tumors, or to treat the mass by hyperthermia. The probe system comprises an elongate member with distal and proximal ends, a handle at the proximal end, and an electrode deployment device positioned at least partially in the elongate member. The electrode deployment device includes at least one retractable electrode having a non-deployed state when positioned in the elongate member and a distended deployed state when advanced from the elongate member, and when deployed has at least one radii of curvature. The electrode is adapted to be inserted into and penetrate tissue, and to extend to a selected mass. The electrode is advanceable in and out of the elongate member.

B. The Prior Art

RYDELL describes an electrosurgical instrument for cutting tissue and coagulating blood. The instrument of Rydell is used for surgical techniques such as enlarging the opening of the



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papilla for passing gall stones or for removing polyps from the colon. The instrument includes an elongated, flexible member with proximal and distal ends. A plurality of lumens extend between the ends of the member. A bullet-shaped ceramic tip is affixed to the distal end of the member. The exterior surface of the tip is covered with a conductive layer forming a first electrode. The tip has a centrally disposed longitudinal bore in the side wall. In the "cut" mode, a wire is extended through the longitudinal bore and acts as the active electrode in a bipolar pair. An endoscope is used to locate the instrument through an appropriate body orifice to the body cavity where the surgery is to take place.

C. Analysis

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

Rydell fails to teach an electrode having a non-deployed state when positioned in the elongate member and a distended deployed state when advanced from the elongate member. As can best be seen in Figure 4, the conformation of the wire electrode of Rydell is the same for the deployed electrode as for the electrode positioned in the elongated tubular member. Rydell further fails to teach that the electrode, when deployed, has at least one radii of curvature. The electrode of Rydell is a wire that extends longitudinally so that the proximal end projects outwardly through an opening formed in the tip of the elongated tubular member. Furthermore, the electrode of Rydell is deployed using a spring-loaded plunger from the elongate member at an angle determined by the opening formed in the tip member and



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does not alter direction from the angle determined by the opening as the electrode is advanced from the elongate member.

Accordingly, Applicants submit that the standard of strict identity to maintain a rejection under 35 U.S.C. §102 has not been met. Withdrawal of the rejections under 35 U.S.C. §102(b) is respectfully requested.

VI. Rejections under 35 C.F.R. §103

Claim 33 was rejected under 35 U.S.C. §103 as allegedly obvious over either Abele *et al.* (U.S. Patent No. 5,403,311) or Durgin, Jr. *et al.* (U.S. Patent No. 5,336,222) in view of Rydell. This rejection is respectfully traversed.

A. The Present Invention

The present invention is described above.

B. The Prior Art

RYDELL is described above.

ABELE *ET AL.* describe a flexible, pushable, elongated electro-coagulation catheter. The distal tip of the catheter has a tissue-penetrable RF current electro-coagulation probe projectable from the catheter. The distal end of the catheter has a second electrode for contact with the tissue to operate in bipolar mode. The probe may further be a needle for delivery of fluid to the tissue.

DURGIN, JR. *ET AL.* describe an integrated catheter assembly for hemostatic, injection and irrigation therapies. The assembly includes a catheter with a bipolar electrode tip and an injection needle. The electrode tip has a body portion with a



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hemispherical distal end. The needle extends through a catheter lumen and the body portion.

C. Analysis

According to the M.P.E.P. § 2143, one of the three basic criteria to establish a prima facie case of obviousness, is that "the prior art references (or references when combined) must teach or suggest all the claim limitations." It is Applicants' position that the references fail to teach or suggest all the claim limitations of the present invention.

As discussed above, Rydell fails to disclose an electrode having a non-deployed state when positioned in the elongate member and a distended deployed state when advanced from the elongate member. Rydell also fails to show or suggest an electrode that when deployed has at least one radii of curvature. The electrode of Rydell deploys longitudinally through a bore in the side wall of the bullet-shaped ceramic tip.

The disclosures of Abele *et al.* or Durgin, Jr. *et al.* do not make up for this deficiency. Abele *et al.* teach a retractable, rigid electro-coagulation needle or probe mounted on the distal end of a catheter. The probe does not have a non-deployed and deployed state. The probe is merely pushed through the opening in the catheter into the tissue. Further, the probe does not have at least one radii of curvature when deployed.

Durgin, Jr. *et al.* teach electrodes that are positioned on the exterior of the body portion, not extended therefrom. The electrodes are not positioned in the elongate member and do not deploy from the elongate member. Further, as the electrodes do



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not extend from the elongate member, they do not exhibit at least one radii of curvature.

The combined teachings of Rydell, Abele *et al.*, and Durgin, Jr. *et al.* nowhere show or suggest an electrode having a non-deployed state when positioned in the elongate member and a distended deployed state when advanced from the elongate member. Nor do the references show or suggest that the electrode, when deployed, has at least one radii of curvature.

Because none of the references alone or in combination teaches all the claim limitations of the present invention, the standard for obviousness has not been met. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

VII. Obviousness-Type Double Patenting Rejection

Claim 33 was rejected under the judicially created doctrine of obviousness-type double patenting as being directed to an invention not patentably distinct from claims 1, 7, and 17 of U.S. Patent No. 5,935,123.

A Terminal Disclaimer prepared in accordance with 37 C.F.R. §1.321(b) and (c) is enclosed. The signed Terminal Disclaimer obviates the above obviousness-type double patenting rejection.

**CONCLUSION**

In view of the foregoing, Applicants submit that the claim pending in the application complies with the requirements of 35 U.S.C. §112 and patentably defines over the prior art. A Notice of Allowance is therefore respectfully requested.



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The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

Jacqueline F Mahoney

Date: January 18, 2002

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

This application is a continuation of application serial No. 09/364,203 entitled "RF TREATMENT APPARATUS," filed August [16]30, 1999, now pending, which is a continuation of application serial No. 08/623,652 entitled "RF TREATMENT APPARATUS," filed March 29, 1996, now U.S. Patent No. 5,935,123, which is a continuation of application serial no. 08/295,166 entitled "RF TREATMENT APPARATUS," filed August 24, 1994[.], now U.S. Patent No. 5,599,345, which is a continuation-in-part of Application serial No. 08/148,439 entitled "DEVICE FOR TREATING CANCER AND NON-MALIGNANT TUMORS AND METHODS," filed November 08, 1993, now U.S. Patent No. 5,548,597, by Edwards *et al.* each of which is incorporated herein by reference.

33. A probe system comprising:

an elongate member with a distal end and a proximal end;

a handle at the proximal end of the elongate member; [and]

an electrode deployment device positioned at least partially in the elongate member and including at least one retractable electrode that is adapted to be inserted into tissue, [penetrates]adapted to penetrate tissue, and [extends]is adapted to extend to a selected mass, the electrode having a non-deployed state when positioned in the elongate member and a distended deployed state[d] when advanced from the elongate member[,]; and

the at least one deployed electrode [have]has at least one [radii] radius of curvature; [and]

wherein the at least one electrode is advanceable in and out of the elongate member.



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